



A PRACTICE GREENHEALTH PROGRAM

Guidance to Achieve HH Safer Chemicals Challenge PVC and DEHP Reduction in Medical Devices

Version 2.0

December 2016

This document provides guidance for institutions and suppliers wishing to meet the requirements for the PVC and DEHP Reduction goal of the Healthier Hospitals Safer Chemicals Challenge, Version 2.0.

PVC and DEHP Reduction Goal

Eliminate PVC and DEHP from at least two product categories.

Product categories include:

1. Breast Pumps and accessories,
2. Enteral Nutrition Products, including all tubing,
3. Parenteral Infusion Devices and Sets,
4. General Urological (irrigation/urology sets and solutions, urinary catheters),
5. Exam Gloves,
6. Vascular Catheters, including Umbilical Vessel Catheters, and
7. Nasogastric Tubes

Definitions:

Polyvinyl chloride (PVC), or vinyl, is a synthetic thermoplastic material made by polymerizing vinyl chloride. The properties of the material depend on the additives, including plasticizers. PVC has a wide array of uses.¹

DEHP, or di(2-ethylhexyl)phthalate, is a softener often used in polyvinyl chloride (PVC) plastics. Unplasticized PVC is hard and brittle at room temperature. A plasticizer is typically added to increase the flexibility of the polymer. DEHP is the plasticizer used most often in PVC medical devices.

¹ PVC and Phthalates, The Issue, Health Care Without Harm, http://www.noharm.org/us_canada/issues/toxins/pvc_phthalates/, accessed September 2015.

Rationale: PVC requires highly toxic inputs during manufacture, and, in some cases, toxic additives to achieve key performance characteristics. It can also result in the formation of a variety of highly toxic chemicals during disposal by incineration. PVC can be difficult to recycle because it must be completely segregated from other plastics in the general waste stream. DEHP is a reproductive and developmental toxicant that can leach out of medical devices, threatening some patients exposed to the chemical. The FDA has recommended a reduction in exposure to DEHP, particularly for vulnerable patients. This goal requires devices to be both PVC- and DEHP-free.

Scope of Products Covered

Exemptions and De Minimis Levels:

PVC: Very small components containing less than 1% of PVC by weight of the product are allowed. PVC tubing is **not** exempt.

DEHP: The de minimis level for DEHP in homogenous materials is 1000 ppm.

Note: The goal does not include packaging.

1. Breast Pumps and accessories

Definition: Breast pumps and accessories include the breast pump mechanism and all component parts of the breast pump.

2. Enteral Nutrition Products

Definition: Enteral nutrition products include containers of nutritional formula, tubing, syringes, and pumps.

3. Parenteral Infusion Devices and Sets

Definition: Parenteral infusion devices and sets, including pumps.

4. General Urological

Definition: General urological products include individual items or urologic sets and solutions, as well as their component parts, used for urinary catheterization or irrigation.

5. Gloves

Definition: Exam gloves include general examination, surgical, and general purpose gloves.

6. Vascular Catheters

Definition: Vascular catheters, including umbilical vessel catheters.

7. Nasogastric Tubes

Definition: Nasogastric tubes.

Verification:

Suppliers should provide, upon request:

- laboratory testing data from an accredited lab, verifying compliance; or
- a formal declaration stating that the product supplied does not contain PVC or DEHP, as required by this Guidance; the declaration must be written, signed, and dated by the manufacturer on the manufacturer's letterhead.